04/24/24 BIG PHARMA

Novartis Accused of Promoting Asthma Drug for Preterm Labor Despite Brain Risk + More

The Defender's Big Pharma Watch delivers the latest headlines related to pharmaceutical companies and their products, including vaccines, drugs, and medical devices and treatments. The views expressed in the below excerpts from other news sources do not necessarily reflect the views of The Defender. Our goal is to provide readers with breaking news that affects human health and the environment.

By The Defender Staff

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Novartis Accused of Promoting Asthma Drug for Preterm Labor Despite Brain Risk

Reuters reported:

> Novartis (NOVN.S) has been hit with a lawsuit by people with autism and their mothers alleging the drugmaker illegally promoted an asthma drug for the treatment of preterm labor despite knowing it was ineffective and could cause abnormal fetal brain development.
>
> The lawsuit, filed last week in Alameda County, California state court, also names the University of California, alleging that a now-deceased professor helped Novartis promote terbutaline for the dangerous off-label use.
>
> The five plaintiffs include twins born in 1993 and a man born in 2002, along with their mothers. They accuse Novartis and the university of negligence

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and intentional misrepresentation and are seeking unspecified monetary damages.

Novartis sold terbutaline in the United States as an asthma treatment under the brand name Brethine from 1976 to 2001. In the late 1970s, according to the lawsuit, some doctors began experimenting with using it to stop preterm labor, under the theory its muscle-relaxing properties could prevent uterine contractions.

Studies published in 2011 and 2016 showed an association between terbutaline and autism, the complaint said.

New Hampshire's GOP Is Taking a Stand — Against the Polio Vaccine

MotherJones reported:

New Hampshire could soon beat Florida — known for its anti-vaccine Surgeon General — when it comes to loosening vaccine requirements. A first-in-the-nation bill that's already passed New Hampshire's state House, sponsored only by Republican legislators, would end the requirement for parents enrolling kids in childcare to provide documentation of polio and measles vaccination. New Hampshire would be the only state in the U.S. to have such a law, although many states allow religious exemptions to vaccine requirements.

Currently, Republicans control New Hampshire's state House, Senate and governor's office — but that isn't a guarantee that the bill will be signed into law, with GOP Gov. Chris Sununu seemingly flip-flopping when it comes to disease control.

Sununu did sign a bill in 2021 allowing people to use public places and services even if they did not receive the COVID-19 vaccine. But the next year, the governor vetoed a bill that would bar schools from implementing mask mandates.

Ottawa Injects Another $36 Million Into Vaccine Injury Compensation Fund

The Canadian Press reported:

The federal government has added $36.4 million to a program designed to support people who have been seriously injured or killed by vaccines since the end of 2020. The program was announced shortly after COVID-19 shots first became available to the public, and provides financial compensation to people who were adversely affected by Health Canada-approved vaccines.

The Liberals earmarked $75 million for the first five years of the program. To date, a private firm called OXARO has received $56.2 million from Ottawa to run the program and pay out valid claims that originate outside of Quebec. As of December, the firm has paid $11.2 million in compensation.

Quebec has had its own vaccine injury compensation program since 1985, and received $7.75 million when the federal program launched. The Liberal government set aside another $36 million for OXARO and Quebec to cover the next two years of the program as part of the federal budget tabled in the House of Commons last week.

The program was launched during the COVID-19 pandemic but covers injuries and deaths associated with vaccines approved for any illness, as long as they were administered after Dec. 8, 2020.

COVID Vaccine Emails: Here's What the CDC Hid

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Behind Redactions

The Epoch Times reported:

> The U.S. Centers for Disease Control and Prevention (CDC) hid how a woman who suffered chest pain and other symptoms following COVID-19 vaccination received a shot because of a mandate at work, newly obtained documents show.
>
> The agency also redacted how multiple children were diagnosed with Kawasaki Disease after receiving a COVID-19 vaccine, according to the documents.
>
> The Epoch Times obtained more than 1,400 pages of emails from the CDC concerning its Clinical Immunization Safety Assessment (CISA) project, which analyzes post-vaccination problems reported by healthcare providers. The tranche included numerous redactions.
>
> While redactions are allowed under the Freedom of Information Act, there were signs that too much information was being hidden.

Massive Amounts of H5N1 Vaccine Would Be Needed if There's a Bird Flu Pandemic. Can We Make Enough?

STAT News reported:

> The first signs that H5N1 — or any new flu virus — was starting to spread from person to person would trigger a race to produce massive amounts of vaccine to try to mitigate the damage a flu pandemic might be expected to cause. While the 2009 H1N1 pandemic is estimated to have killed about a quarter-million people worldwide — severe flu seasons sometimes kill more — the 1918 Spanish flu pandemic is believed to have killed between 50 million and 100 million people, many times more than COVID-19.
>
> The good news: The world makes a lot of flu vaccines and has been doing it for decades. Regulatory agencies have well-oiled systems to allow manufacturers to update the viruses the vaccines target without having to seek new licenses. The United States even has some H5 vaccine in a stockpile that it believes would offer protection against the version of the H5N1 virus infecting dairy cattle, though there would not be nearly enough doses for the entire country.
>
> The bad news: The current global production capacity isn't close to adequate to vaccinate a large portion of the world's population in the first year of a pandemic. And batches of flu vaccine, often (though not always) produced in hen's eggs, take months to produce.
>
> Experts STAT interviewed suggested that in some respects, the world is better positioned to produce pandemic flu vaccines if the need arises. But a number warned that assuming the successes of COVID vaccine production would automatically influence the speed and scale of pandemic flu vaccine production would be unwise.

Moderna Gets Grant for Vaccine Composition for Varicella-Zoster Virus

Pharmaceutical Technology reported:

> Moderna has been granted a patent for a nucleic acid vaccine that includes RNA polynucleotides encoding varicella zoster virus antigens. The vaccine composition comprises mRNA encoding VZV glycoproteins and a lipid nanoparticle. This innovative vaccine technology could potentially revolutionize the field of immunization. GlobalData's report on Moderna gives a 360-degree view of the company including its patenting strategy.

According to GlobalData's company profile on Moderna, mRNA delivery lipid nanoparticles was a key innovation area identified from patents. Moderna's grant share as of February 2024 was 27%. Grant share is based on the ratio of number of grants to total number of patents.

A recently granted patent (Publication Number: US11918644B2) discloses a vaccine composition designed to target the varicella-zoster virus (VZV) by utilizing a messenger ribonucleic acid (mRNA) encoding specific glycoproteins. The composition includes a lipid nanoparticle with precise proportions of ionizable cationic lipid, neutral lipid, cholesterol, and polyethylene glycol (PEG)-modified lipid. The mRNA in the vaccine composition can be chemically modified to enhance its efficacy, with options such as pseudouridine, N1-methylpseudouridine, and other modifications listed in the claims.

Novartis Dials Up 2024 Sales Outlook, Preps for Key Expansions of 3 Cancer Drugs

Fierce Pharma reported:

Novartis has increased its full-year sales guidance after pulling off a strong first quarter, even though three meds missed analysts' expectations ahead of their key expansion opportunities.

Novartis' $11.8 billion sales in the first quarter marked 11% growth year on year at constant exchange rates and came in 4% above Wall Street's consensus estimates. As a result, Novartis has raised its full-year guidance to now expect sales to grow in the high single to low double digits, up from the previous forecast of mid-single-digit growth.

However, three cancer drugs — Pluvicto, Kisqali and Scemblix, all of which have important new indications lined up in earlier treatment settings — all slightly disappointed during the first three months of 2024.

New Studies Suggest GLP-1 Healthcare Costs Have Only Begun to Climb

STAT News reported:

Spending on GLP-1 drugs like Ozempic and Wegovy ballooned last year and they're set to cost the U.S. healthcare system and the federal government still more this year and beyond, two new reports released Wednesday show.

One study from the American Society of Health-System Pharmacists found that GLP-1 treatments were a main driver of the increase in overall drug spending by health entities such as pharmacies and hospitals last year. In particular, expenditures on Novo Nordisk's semaglutide — sold as Ozempic for diabetes and Wegovy for obesity — doubled to $38.6 billion, making the drug the top-selling medicine in 2023.

New Antibiotics Aren't Being Fully Used, Study Finds

CIDRAP reported:

A new study shows that, despite having newer options for antibiotic-resistant infections, U.S. clinicians are still frequently opting for less optimal older, generic antibiotics.

The study, which was conducted by researchers with the National Institutes of Health and published late last week in the Annals of Internal Medicine, found that, from 2019 to 2021, more than 40% of patients at U.S. hospitals who had infections with difficult-to-treat resistance (DTR) were treated exclusively with traditional antibiotic agents, including antibiotics that were known to be potentially toxic, when newer options were available.

In addition, at more than a third of the hospitals, no patients received any of the next-generation antibiotics for gram-negative infections that have been approved by the U.S . Food and Drug Administration (FDA) since 2014.

The authors of the study say the findings could have significant implications for future antibiotic development and for policymakers who are focused on efforts to fix the broken market for antibiotics.

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